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REMARKS

1. Status of the Claims

Claims 1-283 are pending in this application. Claims 20-27, 41-42, 70-72, 83-85, 112, 138, 164, 176 and 188-276 were previously withdrawn from consideration as being drawn to nonelected inventions. Claims 1, 4, 6-8, 10, 16-19, 29-34, 36-38, 40, 53, 73, and 146 are currently amended. Claims 5, 12, 14, 15, 28, and 35 are currently canceled. Claims 1-4, 6-11, 13, 16-19, 29-34, 36-40, 43-69, 73-82, 86-111, 113-137, 139-163, 165-175, 177-187, and 277-283 are currently pending for prosecution on the merits. These claims stand rejected under 35 U.S.C. §§112 and 103 (a). The 35 U.S.C. §112 and 103 (a) rejections are summarized in a table in the attached Appendix 1.

2. Rejections Under 35 U.S.C. §112

The Examiner has rejected claims 1-4, 8-15, 28-40, 43-69, 73-82, and 151 under 35 U.S.C. §112, second paragraph (OA ¶ 5). Applicants have amended claims 1, 53, and 73, and submit these amendments fully address the rejection of OA ¶5, and respectfully request a withdrawal of this rejection.

The Examiner has also rejected claims 1-4, 8-15, 28-40, 43-69, 73-82, 88, 93, 96, 115, 120, 123, 141, 146, 149, 167, 172, 179, and 185 under 35 U.S.C. §112, second paragraph (OA ¶ 7). Applicants have amended claims 1, 4, 53, and 73, and submit these amendments fully address the rejections of OA¶7.

Examiner asserts that the limitation "wherein the ART includes all fertility treatments in which both eggs and sperm are handled" is not supported in the specification (OA¶7). Applicant submits it is well-known in the art that ART ("artificial reproductive technology") includes all fertility treatments in which both eggs and sperm are handled. Exhibit 1 *"Assisted Reproductive Technology description by the Center for Disease Control."* Furthermore, Applicant's specification does not limit ART to only in vitro fertilization methods, and in fact states "...ART cycles, including, but not limited to in vitro fertilization." (Specification pg. 4, ll. 15-16, 30-31; pg. 6, ll. 31-32; pg. 7, ll. 4-5; 9-10) Pursuant MPEP §2144.03, Applicant requests Examiner to take official notice that term ART includes all fertility treatments in which both eggs and sperm are handled. As such, Applicant respectfully requests a withdrawal of this rejection.

Finally, Applicant addresses Examiner's rejection based on lack of enablement in OA¶8. Applicants currently amend claim 1 to require that the ratio of Th1 immune response to Th2 immune response in the subject is determined by measuring a ratio of the level of a Th1 cytokine to a level of a Th2 cytokine, wherein the method of reducing the ratio of the Th1 immune response to the Th2 immune response is achieved by suppressing the Th1 cytokines in the subject by administering an effective dose of a Th1 cytokine antagonist, wherein the Th1 cytokine antagonist is selected from a group consisting of IL-1 antagonists, IL-2 antagonists, TNF-α antagonists, and IFN-α antagonists, wherein the Th1 cytokines are selected from the group consisting of IL-1, IL-2, TNF- α, and IFN- α, and wherein the Th2 cytokines are selected from the group consisting of IL-4, IL-5, IL-6, and IL-10 . Claims 53 and 73 are currently amended to require that the ratio of Th1 immune response to Th2 immune response in the subject is determined by measuring a ratio of the level of a Th1 cytokine to a Th2 cytokine, wherein the Th1 cytokines are selected from the group consisting of IL-1, IL-2, TNF-α, and IFN-α, and wherein the Th2 cytokines are selected from the group consisting of IL-4, IL-5, IL-6, and IL-10. Applicants believe currently amended claim 1 identifies specific Th1 cytokine antagonists that suppress specific Th1 cytokines resulting in an immune response of the present invention. Furthermore, currently amended claims 1, 53 and 73 identify specific Th1 and Th2 cytokines of the present invention. Applicants therefore request withdrawal of rejection under 35 U.S.C. §112.

3. Declaration Under 37 C.F.R. 1.131 and Rejections Under 35 U.S.C. §103(a)

The Examiner has rejected the claims identified in the attached Appendix in paragraphs 9, 10, 13-15, and 19-22 and 23-29 of the June 27, 2007 Office Action. The rejections in paragraphs 10, 13, 14, 15, 19, 20, 21, and 22 require the combination of Pluenneke with other references identified in the Office Action. The rejections recited in paragraphs 23-29 do not require Pluenneke. Rather these rejections require a combination of Finck with other references.

In Applicants prior response dated May 23, 2006, it submitted a Combined Declaration of Joint Inventors under 37 C.F.R. §131 to swear behind Pluenneke. For the

reasons set forth in the May 23, 2006 Reply, Pluenneke is prior art under 35 U.S.C. §102 (e) and is not a statutory bar.

The examiner has objected to the May 23, 2006 Declaration stating that Applicants must file a separate petition under 37 C.F.R. §1.183 indicating that inventor Alan E. Beer is deceased, accordingly Applicant submits such a petition with this Reply.

The examiner also objected to the May 23, 2006 Declaration indicating, that to be persuasive the declaration must show inventive collaboration by all of the joint inventors, and provide evidence of the instant invention encompassing the full breadth of the invention. Applicants submit a Supplemental Declaration of Combined Joint Inventors under 37 C.F.R. §1.131 to address Examiner's concerns. Specifically, the Supplemental Declaration avers that at the time of conception the joint inventors contemplated in vivo methods of treatment that were worked on diligently from prior the Critical Date up to the time of filing. Evidence of successful in vivo applications is expressly provided in the specification under Individual Case Studies, pgs. 26-28.

Additionally, Applicants' Supplemental Declaration avers that several commercially available TNF-α antagonists were contemplated before the Critical Date (Supp. Decl. ¶8), and were not limited to treatment with the TNF-α antagonists entanercept.

Applicants submit this newly submitted Supplemental Declaration addresses Examiner's objections to the sufficiency of the first declaration, and, therefore, Applicants request that Pluenneke should be excluded as a reference by virtue of this Supplemental Declaration. Further, the Examiner cannot rely on Pluenneke in any combination, and, therefore, Applicants respectfully request a withdrawal of all the rejections under 35 U.S.C. §103 (a) in paragraphs 10, 13, 14, 15, 19, 20, 21, and 22 of the present Office Action as they all require Pluenneke.

As for the rejections not requiring Pluenneke, Applicants amended independent claims 53 and 73 to include the steps of measuring the Th1 immune response and the Th2 immune response, wherein the ratio of Th1 immune response to Th2 immune response in the subject is determined by measuring a ratio of the level of a Th1 cytokine to a Th2 cytokine, the Th1 and Th2 cytokines consisting of TNF-α. These steps are not disclosed or suggested by any of the cited references applied in paragraphs 23-29 of the present

Office Action, and, therefore, Applicants submit the rejected claims are patentable over these combination of references and respectfully request withdrawal of the rejection of these claims under 35 U.S.C. §103(a).

4. Conclusions

In view of the foregoing, Applicants submit the claims are in condition for allowance and respectfully request an early notice of the same.

Respectfully submitted,

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